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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,366	04/23/2001	Marie-Christine Etienne	REF/ETIENNE/698CIP	2300

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EXAMINER
TRAVERS, RUSSELL S

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/839,366	Applicant(s) Etienne
	Examiner R.S. Travers J.D., Ph.D.	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 30, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-22* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 1-22 are presented for examination.

The amendment filed May 5, 2003 has been received and entered into the file.

Applicant's arguments filed May 5, 2003 have been fully considered but they are not deemed to be persuasive.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1-22 are rejected under 35 U.S.C. § 101 because the claimed invention, setting forth and incredible utility, lacks patentable utility.

The instant application contains an invention directed to treating various conditions with compounds capable of producing the observed symptomology; wherein these compounds are administered at undetectable levels. Applicants have supplied only anecdotal evidence supporting the therapy herein claims. It is noted that Petit et al (provided in parent) and Labrecque et al published studies employing the same manner of therapy herein claimed and found no therapeutic benefit residing therein. The skilled artisan would view a randomized, double-blind, placebo-controlled clinical trial more convincing than antidotal accounts related by Applicants. Absent information, as well grounded as that provided by Examiner cited prior art, the instant claims fail to illustrate the presence of identifiable utility.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that defines either "active principle, R", or, those compounds that are "a poison, or part of a poison". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of "active principle, R", or, those compounds that are "a poison, or part of a poison" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "active principle, R", or, those compounds that are "a poison, or part of a poison", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 1-11, 13-19 and 20-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11, 13-19 and 20-22 are rendered indefinite by the phrases "active principle, R", or, those compounds that are "a poison, or part of a poison" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining "active principle, R", or, those compounds that are "a poison, or part of a poison" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Labrecque et al Tetau and Applicants' admission on the record, all of record.

Labrecque et al and Tetau teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically divalent metal ions. These medicaments are taught as useful for treating viral diseases. Claims 1-22, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by Tetau teaching employment of divalent metal ions to effect the desired therapeutic goals. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

Claims 1-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Cazin et al, Besnouin and Applicants' admission on the record, all of record.

Cazin et al and Besnouin teach the homeopathic compounds herein claimed in combination with various pharmaceutical carriers and excipients in a dosage form, specifically arsenic compounds. These medicaments are taught as useful for producing the retention of, or causing excretion of compounds responsible for disease. Claims 8-28, and the primary reference, differ as to:

1) the metal ion employed, and

2) the proposed mechanism by which the homeopathic therapy effected the desired therapeutic regimen.

The first deficiency is cured by information possessed by the skilled artisan and Besnouin teaching the employment of calcium ions to effect the desired therapy. Additionally, Cazin teaches effecting the desired therapeutic goal by employing arsenic, residing in the same chemical period as the claimed antimony. The skilled artisan would have expected compounds residing in the same chemical period to possess therapeutically equivalent effects. The second deficiency is cured by cured by Applicants' admission that the xCH factor effects the therapy in a similar and predictable way. Thus, the skilled artisan possessing the "Hahnemannian homeopathic dilution (xCH)", or "Korsakowian homeopathic dilution (xCH)" would possess the

knowledge to effect the required therapy, and be motivated to apply such therapy, regardless the etiology.

As stated in the instant specification, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients.

RESPONSE TO ARGUMENTS

Arguments presented to rebut the rejection under 35 USC 101 are unconvincing. Those prior art teachings recited in previous office actions were provided to illustrate the repeated failure of homoeopathic regimens to provide therapeutic benefit. Examiner cited prior art teaches not only failure of studies almost identical to those herein recited, but casts doubt on the efficacy for any homoeopathic regimen: hence the rejection under 35 USC 101. Studies provided by Examiner illustrate a general failure of regimens employing the therapeutic template herein employed, and places a burden of proof on the Applicant to illustrate predictable therapeutic benefits residing in the regimen herein recited. That a procedure was therapeutically applied in the prior art provides a teaching for the obviation of such procedures.

Examiner finds arguments rebutting the rejection under 35 USC 112, first and second paragraph unconvincing. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first, and second paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are

an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Arguments rebutting the rejection under 35 USC 103 are unconvincing. Attention is directed to Labrecque et al teaching administration of a 7 CH antimony regimen to provide therapeutic benefit. Examiner notes therapeutic benefits were provided by the administered regimen; albeit at those levels provided by the placebo effect.

Examiner fully understands those elements required to obviate the instant invention. The Examiner cited prior art teaches the administration of the same compound, antimony; in essentially the same manner, 7CH; to provide essentially the same result, to restore normal function, healing of a viral disease as herein envisioned; warts (see specification page 18).

The instant claims are directed to effecting a biochemical pathway with an old and well known compound. Arguments that Applicant's claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation fails to impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn

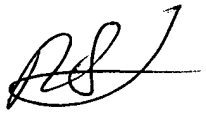
to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may in fact be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known, rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103. Those admissions relied on by the Examiner are directed to the basic fundamentals of homeopathic therapy, not elements of the instant invention herein disclosed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE

MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
Art Unit 1617